

July 18, 2005

Dockets Management Branch  
Food and Drug Administration  
Department of Health and Human Services  
Rm. 1-23 12420 Parklawn Dr.  
Rockville, MD 20857

2794 5 JUL 26 A9:31

### Citizen Petition

The undersigned submits this petition under Title 21 CFR part 10.30 of the Federal Food Drug and Cosmetic Act to request the Commissioner of Food and Drugs to issue a regulation establishing a standard of identity for Pure Birch Syrup and Birch Breakfast-Style Syrup using added fructose (Appendix A).

The sap of the birch tree (genus *betula*) is sweet and is tapped in spring for syrup production and other uses in the northern boreal forests of the United States, Canada, Europe and Russia. Alaska is the world leader in birch syrup production. The Alaska Birch Syrupmakers Association (ABSA) (Appendix B) has developed best practices and production standards for product quality assurance (Appendix C). The birch syrup industry is growing internationally and there is now a need for a federally recognized standard of identity to establish product consistency. This will provide consumers with quality assurance and protect the integrity of the birch syrup industry.

Commercial Alaskan birch syrup producers make two distinctly different products from the sap of the birch tree; a 100 percent Pure Birch Syrup and a Birch Breakfast-Style Syrup by adding fructose, both resulting in an end product that contains a minimum of 66 percent sugars by weight and a maximum of 74 percent sugars by weight, as described in Appendix A. Through production and marketing research and development, Alaskan birch syrup producers have found that syrup containing less than 66 percent sugars does not attain an acceptable viscosity and syrup containing greater than 74 percent sugars has the tendency to become unstable and crystallize; thereby reducing its marketability.

These two distinctive Birch Syrups have been an industry standard for 15 years. However there are producers within the state of Alaska and in Canada, and possibly elsewhere, who do not produce and represent these two different birch syrups based on these standards. Currently there is more demand for these two birch syrups than there is product available and this demand is growing regionally, nationally and internationally. This is a problem because of the very real potential for inferior products reaching the market and misleading consumers, ultimately leading to customer dissatisfaction.

Furthermore, in the international market, importers and exporters do not have a standard by which to categorize pure birch syrup or birch breakfast style syrup, which has lead to birch syrups being scheduled under a general category or "other" category under the World Harmonized System of the World Trade Organization by a Japanese importer (Appendix D). A FDA standard of identity would pave the way for rescheduling birch

2005P-0295

CP 1

syrups under the World Harmonized System and help in dealing with export and import issues.

A FDA standard of identity will help promote the industry, and ensure consumer confidence, by bringing consistency and quality assurance to the end product.

A claim for environmental impact exclusion under 21 CFR part 25.32 is requested for the issuance of these two food standards.

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Signed: Dulce Ben-East Date: 7/18/05

Dulce Ben-East  
President, Alaska Birch Syrupmakers Association  
P.O. Box 877372  
Wasilla, AK 99867  
(907) 373-1309

## Appendix A

### Proposed Definitions for Birch Syrup and Birch Breakfast-Style Syrup

**Submitted by:** The Alaska Birch Syrupmakers Association

P.O. Box 877372

Wasilla, AK 99867

**Contact:** Dulce Ben-East, President (907) 373-1309

#### **Definition:**

**Birch Syrup** is the liquid food derived by concentration and cooking of the sap of the birch tree (genus *Betula*). Birch Syrup contains not less than 66 percent (degrees brix) and not more than 74 percent (degrees brix) by weight of total soluble solids, chiefly sugars found naturally in birch sap. Birch syrup shall be fabricated to industry standards to preserve the birch flavor and result in a food that is safe and suitable.

The name **Birch Syrup** or **Pure Birch Syrup** must be applied to syrup containing only pure birch sap concentrated to at least 66 percent (degrees brix) and not more than 74 percent dissolved solids by weight, chiefly sugars. To be labeled **Birch Syrup** or **Pure Birch Syrup**, the syrup must contain only birch sap processed to industry standards so that no trace metals, minerals, water, proteins, or other chemicals are added inadvertently or intentionally, with the exception of defoaming agents added during sap concentration.

The name **Birch Breakfast-Style Syrup** must be applied to syrup containing birch sap concentrated to no less than 40 percent (degrees brix) of dissolved solids, chiefly sugars and fructose, which can be derived from other plants. The finished syrup must be of at least 66 percent and not more than 74 percent dissolved solids by weight, chiefly sugars. To be labeled **Birch Breakfast-Style Syrup**, the syrup may only contain the acceptable amount of added fructose, and birch sap processed to industry standards, so that no trace metals, minerals, water, proteins, or other chemicals are added inadvertently or intentionally with the exception of defoaming agents added during sap concentration.

#### **Label Declaration:**

The words "**Birch Syrup**" or "**Pure Birch Syrup**" must appear on containers of "**Pure Birch Syrup**", as defined, with allowance that the place of origin may be inserted, i.e. "**Pure Alaska Birch Syrup**". **Pure Birch Syrup** containers shall declare "100 % Pure Birch Syrup" under the list of ingredients. The words "**Birch Breakfast-Style Syrup**" must appear on containers of birch syrup blended with fructose, with the allowance that the place of origin may be inserted, i.e. "**Alaska Birch Breakfast-Style Syrup**". **Birch Breakfast-Style Syrup** containers must declare "cooked birch sap" and "fructose" under the list of ingredients.

If the syrup produced contains birch sap concentrated to less than 40 percent (degrees brix) dissolved solids, chiefly sugars it shall not be labeled as "**Birch Syrup**" or "**Birch Breakfast-Style Syrup**" or any variation thereof, and shall be labeled according to FDA guidelines for Table Syrup.

## **Appendix B**

### **Alaska Birch Syrupmakers Association Member Roster**

#### **Full Members:**

##### **Birch Boy Products**

Contact: Susie and Danny Humphrey  
Address: PO Box 637, 18 Mile  
Haines, AK 99827  
Phone: 907-767-5660  
Fax: 907-767-5660  
Email: [birchboy@aptalaska.net](mailto:birchboy@aptalaska.net)  
Web: [www.birchboy.com](http://www.birchboy.com)

##### **Chickaloon Birch Syrup**

Contact: Jim Garhart  
Address: PO Box 1105  
Chickaloon, AK 99674  
Phone: 907 745-0707

##### **Kahiltna Birchworks**

Contact: Michael East and Dulce Ben-East  
Address: PO Box 2267  
Palmer, AK 99645-2267  
Phone: 907-373-1309  
Fax: 907-373-1359  
Email: [dulce@alaskabirchsyrop.com](mailto:dulce@alaskabirchsyrop.com)  
Web: [www.alaskabirchsyrop.com](http://www.alaskabirchsyrop.com)

##### **Knik Birch Syrup Company**

Contact: Charlene Montague  
Address: PO Box 87732  
Wasilla, AK 99687-7373  
Phone: 907-373-2935  
Fax: 907-373-2936  
Email: [kbsc@mtaonline.net](mailto:kbsc@mtaonline.net)  
Web: [www.knikbirchsyrop.com](http://www.knikbirchsyrop.com)

**Associate Members:**

**Alaska Boreal Forest Council**

Contact: Scott Bates

Phone: 907-457-8453

Email: [scott.abfc@ak.net](mailto:scott.abfc@ak.net)

Web: [www.akborealforest.org](http://www.akborealforest.org)

**Marlene Cameron**

Contact: Marlene Cameron

Phone: (907) 232-0577

Email: [marlene@ak.net](mailto:marlene@ak.net)

## **Appendix C**

### **Alaska Birch Syrupmakers' Association BEST PRACTICES For Producing Quality Birch Syrup**

#### **Guidelines and Recommendations**

##### **A. Tree Tapping**

1. Time to tap varies by location; usually first part of April.
2. Tap holes: 1 ½ - 1 ¾ " deep, slight upward angle, using a 5/16-7/16" bit, depending on spout used.
3. Location of hole: 2-4 feet high, to the side of previous holes
4. Tap healthy trees; 8" diameter-at-breast-height (DBH) or larger
5. Do not tap trees that have ever had pesticides sprayed on or around.
6. One tap per tree.
7. Use plastic, nylon, or steel spouts, or tubing supplies commercially available through local syrup equipment suppliers.
8. Do not drive taps too deep – wood can split causing leakage.
9. Sterilize taps before use.
10. Tap trees when the sap flow is continuous.
11. Tap trees only where access is good and equipment will not compromise ground cover. Minimize damage to trails during break-up.
12. Remove spouts at end of season; may spray hole with pure water. Cork tapped holes upon removal with appropriate sized cork (available through local suppliers).

##### **B. Sap Collection**

1. Use equipment appropriate for trail conditions. On public lands follow regulations.
2. Use stainless or food-grade plastic collection containers and storage tanks. Do not use containers previously containing toxic materials.
3. Use only food grade hose and lines or standard maple tubing (no garden hoses!)
4. Collect sap daily.
5. Clean collection tanks and pumps daily.
6. Discontinue collection when yeast appears on taps and sap turns cloudy. Once sap has begun to turn it should no longer be used for bottled pure birch syrup.

##### **C. Sap Storage**

1. Use FDA approved food grade poly, stainless, or glass-lined tanks.
2. Process all sap daily in the order in which it was gathered. Keep stored sap below 42 degrees F and out of direct sun.
3. Clean sap storage tanks daily.
4. Monitor sap brix (sugar content) with refractometer or hydrometer.
5. Filter all sap through a water filter no larger than 5 micron.

**D. Syrup Production -- Reverse Osmosis (RO) - optional equipment**

1. Follow manufacturer's instructions for operating and cleaning.
2. Keep RO-concentrated sap cool and out of direct sunlight. Process as soon as possible to prevent spoilage and yeast growth. Do not store concentrated sap.
3. Use FDA approved storage tank for concentrated sap.
4. Use food-grade lines, fittings, and valves on RO.
5. Never use chlorine bleach for cleaning tanks or lines – it will compromise RO membranes.

**E. Syrup Production -- Evaporator**

1. Use standard or modified maple syrup evaporators (wood, oil, or gas-fired) with tig-welded or lead-free soldered pans.
2. Run sap through hot and shallow, using consistent heat to establish proper gradient.
3. Clean evaporator daily, using standard pan cleaners available through local suppliers.
4. Rinse often and thoroughly.
5. Filter sap back into cleaned pan.

**F. Syrup Finishing**

1. Evaporate syrup to minimum of 66 percent sugar (brix scale) by weight using a calibrated refractometer. Using a thermometer, syrup is reached at approximately 11 degrees F above the boiling point of water (variable by barometric pressure).
2. Hand filter through approved rayon and felt filters OR preferably filter press (available from local suppliers).
3. For filter press use food grade filter-aid (diatomaceous earth) matched to the filter papers used.
4. Heat syrup to a minimum of 180 degrees F, and no higher than 190 degrees F; immediately hot pack into approved non-metallic food grade container and seal, or bottle (see below).
5. Record date and/or batch number on container. Note quality: brix, flavor, color.
6. Cool all bottled or packed syrup as quickly as possible and store in a cool, dark place.
7. Bottle syrup between 180-190 degrees F. Use only glass or food grade plastic containers and heat seal lids. Lay container on side for at least 10 seconds after bottling to sterilize lid.

**Appendix D**

**World Harmonized System Chapter 17**  
**Birch Syrup Categorization**

品 目 No.	統計 No.	N A C C S H	品 名 Z	税 率 Rate or Duty				単位 Unit	Description
				規 定 General	協 定 WTO	特 恵 Prefer- ential	暫 定 Tempo- rary		
gar	(1702.40)	210	n	-砂糖を加えたもの	78.5 %又は 53.70円 /kgのうち いずれか 高い税率 (70.5% or 53.70 yen/kg. which- ever is the greater)			KG	Containing added sugar
		230	3	-その他のもの	(50%又 は54円/ kgのうち いずれか 高い税率 (50% or 25yen/ kg. which- ever is the greater)			KG	Other
	1702.50	000	4	果糖(化学的に純粋なものに限る。)	9%	(9%)	無税 Free	KG	Chemically pure fructose
	1702.60			その他の果糖及び果糖水(果糖の 含有量が乾燥状態において全重量 の50%を超えるものに限るものと し、酸化物を除く。)				KG	Other fructose and fructose syr- up, containing in the dry state more than 50% by weight of fructose, excluding invert sugar:
		100	3	1 香味料又は着色料を加えたもの	35%又は 27円/kg のうちい ずれか高 い税率 35% or 27yen/ kg. which ever is the greater	29.8%又 は23円/ kgのうち いずれか 高い税率 29.8% or 23 yen/kg. which- ever is the greater		KG	1 Containing added flavouring or colouring matter
				2 その他のもの	50%又は 54円/kg のうちい ずれか高 い税率 50% or 25yen/ kg. which- ever is the greater			KG	2 Other

), con-  
t least  
weight  
in. au-  
ing or

THIS IS THE CURRENT CLASSIFICATION  
FOR PURE BIRCH SYRUP

2 Other

Nothing in  
USA column  
Breakfast  
Style

Tax 50%  
against products  
value including  
shipping charge.